# **EXHIBIT 1**

# UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming

MDL No. 2666 (JNE/FLN)

Products Liability Litigation

This Document Relates to

All Cases

LETTER OF REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE TO THE APPROPRIATE JUDICIAL AUTHORITIES IN AUSTRALIA

The United States District Court for the District of Minnesota presents its compliments to the Principal Registrar of the Supreme Court of Western Australia and requests international judicial assistance for the taking of evidence and the production of documents to be used in a civil proceeding before this Court in the above-captioned matter. This Court requests the assistance described herein as necessary in the interests of justice. The assistance requested is for the Supreme Court of Western Australia to compel by your proper and usual process the below-named individual to submit to providing evidence and producing documents.

 Dr. Kiran Dasari, Royal Perth Hospital, 197 Wellington Street, Perth WA 6000 Australia ("Dr. Dasari")

Dr. Dasari is a nonparty to the above-captioned litigation and is material and necessary to aid in the resolution of the matter.

This Court affirms that:

- 1. This Letter of Request is sent to the Principal Registrar of the Supreme Court of Western Australia, by the United States District Court for the District of Minnesota pursuant to, and in conformity with 28 U.S.C. § 1781, Article III of the Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, the Hague, 18 March 1970, and Australian law;
- 2. The requesting Court is a competent court in both law and equity, has jurisdiction over this action, and has the authority to compel the appearance of and production of documents by corporations and individuals within its jurisdiction;
- 3. This request is issued pursuant to the rules and procedures applicable within this Court's jurisdiction; and
- 4. The documents and evidence sought are relevant to the matters at issue in this action, are anticipated to be used at trial, are not available from any other source, and cannot be obtained without the assistance of the Supreme Court of Western Australia.

In light of international law and the comity that exists between the United States and Australia, the undersigned respectfully issues this Letter of Request for international assistance. The requesting Court provides the additional information below in support of its request.

# I. THE PARTIES AND THEIR REPRESENTATIVES

The defendants are the 3M<sup>TM</sup> and Arizant Healthcare Inc. ("Defendants"), the designers and manufacturers of the Bair Hugger<sup>TM</sup> patient warming system ("Bair Hugger system"). Defendants are represented by:

Jerry W. Blackwell, Corey L. Gordon, and Peter J. Goss of Blackwell Burke, P.A., 431 South Seventh Street, Suite 2500, Minneapolis, MN 55415.

Bridget M. Ahmann and Christin Eaton Garcia of Faegre Baker Daniels LLP, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, MN 55402.

The Plaintiffs in the proceedings are patients who allegedly suffered infections while receiving surgical warming from the Bair Hugger system. Plaintiffs are represented by:

#### Co-Lead Counsel:

Michael V. Ciresi and Jan M. Conlin of Ciresi Conlin, LLP, 225 S. 6th St., Suite 4600, Minneapolis, MN 55402;

Anthony J. Nemo and Genevieve M. Zimmerman of Meshbesher & Spence LTD, 1616 Park Avenue South, Minneapolis, MN 55404;

Ben W. Gordon, J. Michael Papantonio of Levin Papantonio, P.A., 316 S. Baylen Street, Suite 600, Pensacola, FL 32502-5996.

# II. <u>BACKGROUND</u>

The Plaintiffs in this MDL litigation are patients who allegedly have experienced post-surgical infections and/or other medical complications following orthopedic or general surgery where a Bair Hugger<sup>TM</sup> patient warming system ("Bair Hugger system") was used. [Master Long-Form Complaint, ¶¶ 20, 22, attached hereto as Exhibit 1.] The Bair Hugger system is an FDA-cleared medical device used to warm patients during surgery in order to maintain the patient's normal body temperature. Plaintiffs allege that the Bair Hugger system caused their post-surgical infections and seek personal injury recovery against Defendants, who Plaintiffs allege designed, manufactured and marketed

the Bair Hugger system used in their respective surgeries. [Master Long-Form Complaint, ¶¶ 23, 24.]

In support of their allegations, Plaintiffs specifically cite and rely on a number of scientific studies that allegedly "document[] the adverse effects of the Bair Hugger." *Id.* at ¶¶ 62-63. These studies were authored by individuals residing in the United States, as well as individuals residing in the United Kingdom and now Australia. Defendants contend that they are entitled to seek evidence and obtain documents that these authors have about the studies relied upon by Plaintiffs, because the study authors themselves disclaim any proof of causation within the context of any particular study.

# III. THE AUTHOR'S RELATIONSHIP WITH PLAINTIFFS AND DEFENDANTS

Dr. Dasari conducted research and published one scientific study relied upon by Plaintiffs in their suit against Defendants. Plaintiffs' Master Long-Form Complaint specifically cites to this and other studies in support of their position that such studies "document[] the adverse effects of the Bair Hugger." [Master Long-Form Complaint, ¶ 62] Certain of these studies were also discussed by Plaintiffs' counsel and witnesses during Plaintiffs' presentation at a Science Day before this Court. Plaintiffs will likely attempt to use these studies as evidence at trial. The Defendants plan to use these studies to support their defense that the Plaintiffs lack scientific evidence that the Bair Hugger warming blanket causes or increases the risk of surgical site infections.

# IV. REQUESTED EVIDENCE

In support of their defense in this lawsuit, Defendants request the following from Dr. Dasari:

- 1. evidence on the topics specific in the attached Appendix A;
- for him to produce the documents specified within the attached
   Appendix B, which are believed to be in Dr. Dasari's possession custody and control.

Defendants contend that the study authors specifically deny that their studies establish that the Bair Hugger warming blanket causes surgical site infections. Because Plaintiffs' rely on these studies, Defendants submit that information in Dr. Dasari's possession about the design, procedures, conduct, data, and findings from the various scientific studies is highly relevant to this dispute and the proper subject of the letters rogatory process. On information and belief, Dr. Dasari possesses documents about design, procedures, conduct, data, and findings from their studies.

After review, this Court has concluded that it is appropriate to seek international judicial assistance to facilitate the taking of evidence and the production of the requested documents because the requested documents are relevant, are anticipated to be used at trial, are not available from any other source and cannot be obtained without the assistance of the Supreme Court of Western Australia.

# V. PARTICIPATION IN DEPOSITIONS BY U.S. COUNSEL IS REQUESTED Defendants request that:

- 1. All original documents provided pursuant to this process be produced for inspection (and copies be allowed to be made) by Defendants at a location to be determined in or nearby around Perth, Australia, or some other place mutually agreeable to the parties, seven (7) days prior to the date appointed for the taking of evidence from Dr. Dasari;
- 2. The Court order that there be examination under oath and that the examination be transcribed, and that the Court appoint any necessary official to oversee the examination of the witness concerning the matters listed in the attached Appendix A at a place and time to be determined; and
- 3. The parties have leave to participate in the examination by their counsel in the United States of America and legal practitioners of the Supreme Court of Western Australia.

# VI. <u>DISCUSSION</u>

Australia and the United States are both signatories to the Hague Convention.

Dr. Dasari is not a party to this litigation, is believed to be a resident of Australia and is subject to the jurisdiction of the Supreme Court of Western Australia. Thus, the procedures of the Hague Convention are the only means by which the requested evidence may be obtained.

The Court finds that letters rogatory are appropriate in this case because

Defendants' requests are narrowly tailored to information that is relevant to its defense
and necessary for the presentation of its case. These requests are described in full in

Appendices A and B.

The evidence that Defendants seek from Dr. Dasari is not available from other sources. The documents requested are his own documents and records. These documents are specific to, and in the exclusive possession of Dr. Dasari. Therefore, in the interests of justice, international judicial assistance is needed to assure the production of this evidence from Dr. Dasari.

# VII. REIMBURSEMENT OF COSTS

Defendants agree to pay and undertake to reimburse any costs and expenses associated with this Request incurred by the Court in executing the same, as well as all reasonable costs and expenses associated with compliance by the witnesses and Plaintiffs with the Court's Order to the extent permitted or allowed under your law and procedure, or which the Court otherwise deems required under the circumstances.

# VIII. RECIPROCITY

The requesting Court stands ready and willing to do the same for the courts of Australia if and when requested.

The Honorable Joan N. Ericksen United State District Judge District of Minnesota

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#### Appendix A for Dr. Kiran Dasari Evidence To Be Given

#### **Background**

- 1. Name, address, and date of birth.
- 2. Education and employment history.
- 3. Use of and knowledge about patient warming devices.
- 4. Factors that influence infection for general and orthopedic surgery.
- 5. Infection control practices.
- 6. Experience designing, conducting, analyzing or writing up studies, including studies of the type published in the article: Dasari, K., et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012; 67:244-49 ("Dasari 2012").

#### Roles and Arrangements For the Study Described In Dasari 2012 ("the Study")

- 7. Role in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the Study.
- 8. The identity of and roles played by others in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the Study.
- 9. Communications with others involved in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the Study.
- 10. Communications with Dr. Scott Augustine about the Study.
- 11. Communications with Augustine Temperature Management about the Study.
- 12. Communications with people representing the location where the Study was conducted about the Study, including the selection of location, operating theatre, and patient warming devices for use in the Study.

## Design and Methods For the Study Described In Dasari 2012 ("the Study")

- 13. Details of and reasons for selecting locations, protocols, procedures, materials, and methods used in the Study.
- 14. Selection, procurement, and condition of the operating theatres, patient warming devices, and other equipment used in the studies described in the Study.

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- 15. Proposed and final designs for the Study, with rationale for changes to study design and protocols, procedures or methods.
- 16. Location where and conditions in which the Study was conducted.
- 17. Details of and reasons for draping, placement of mannequins, and placement of surgeons and/or anesthesiologists during the Study.
- 18. Selection, procurement, and condition of the operating theatre, patient warming devices and other equipment used in the Study.
- 19. Specific set-up of the testing environment for the Study.
- 20. Details of and reasons for selecting the ventilation regimen and thermistors used in the Study, and for placing the thermistors.
- 21. The carrying out of the Study.
- 22. All measurements taken and data collected during the Study.
- 23. How data were recorded.
- 24. Photographs or video recordings taken or made during the Study.

### **Study Results and Analysis**

- 25. Study results, including statistical analysis of the data.
- 26. Preparation of the manuscript for Dasari 2012, including drafts and the roles of coauthors.
- 27. Reviewer comments for the Study, including communications with co-authors regarding reactions and responses to reviewer comments.
- 28. Interpretation of Study results.
- 29. Application of Study results to hospital practices and patient safety.
- 30. Extent to which Study results can be generalized, and in what conditions.
- 31. Limitations to the Study and its conclusions.

#### **Information About Other Studies**

- 32. Information about the funding, selection of operating rooms, selection and procurement of patient warming devices, condition of patient warming devices, arrangements, design, conduct, results, analysis or publication of the studies described in these articles:
  - Albrecht, M., et. al. Forced-air warming: a source of airborne contamination in the operating room? *Orthopedic Rev.* 2009; 1:e28
  - Albrecht, M., et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2011: 39:321-28
  - Belani, K., et al. Patient warming excess heat: The effects on orthopedic operating room ventilation performance. *Anesth Analg.* 2013; 117(2):406-11
  - Legg, A., et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? *J Bone and Joint Surg.-Br.*, 2012; 94-B:254-56
  - Legg, A., et al. Forced-air patient warming blankets disrupt unidirectional airflow. *Bone Joint J.* 2013; 95-B:407-10
  - McGovern, P., et al. Forced-air warming and ultra-clean ventilation do not mix. *J bone and Joint Surg-Br*. 2011; 93(11):1537 44
  - Reed, M., et al. Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions. *Am Assoc Nurse Anesth. I.* 2013;81:275-80
  - Wood, A., et al. Infection control hazards associated with the use of forced-air warming in operating theatres. *J Hosp Infect*. 2014;1-9

# Appendix B Request for Documents to Dr. Kiran Dasari

Defendants 3M Company and Arizant Healthcare, Inc. request that the documents in your possession, custody or control described below be produced by you.

#### **Documents To Be Produced**

#### **Author's Background**

1. Any curriculum vitae or resume produced by you since 2012.

#### **Documents Relating to Study Initiation and Protocols, Procedures and Methods**

- 2. Communications between you, Mark Albrecht and Mark Harper regarding the design of the article titled "Effect of forced-air warming on the performance of operating theatre laminar flow ventilation," published in Anaesthesia 2012, 76, 244-249 (referred to as "Dasari 2012" or "the Study"), on the subject of the design of the Study.
- 3. Communications between you and Dr. Scott Augustine regarding the subject of the design of the Study.
- 4. Communications between and among you and Augustine Temperature Management<sup>1</sup> regarding the design of the Study.
- 5. Communications between you and Dr. Scott Augustine regarding the funding for the Study.
- 6. Communications between and among you and Augustine Temperature Management regarding the subject of funding for the study
- 7. Records or registers of consulting fees, expense reimbursement, and other compensation paid to you by Dr. Scott Augustine for your work on the Study.
- 8. Records or registers of consulting fees, expense reimbursement, and other compensation paid to you by Augustine Temperature Management for your work on the Study.
- 9. Agreements between you and Dr. Scott Augustine for your work on the Study.
- 10. Agreements between you and Augustine Temperature Management for your work on the Study.
- 11. Communications between you and the Royal Sussex County Hospital, before the Study was conducted, about the Study.

<sup>&</sup>lt;sup>1</sup> In the "Competing Interests" section of Dasari 2012, reference is made to "Augustine Temperature Management." That term is used in this document. That term also should be read to include also "August Temperature Management LLC," to the extent this is a different corporate entity.

- 12. Documents evidencing consent by the Royal Sussex County Hospital about the Study.
- 13. Communications between you and the Royal Sussex County Hospital, after the Study was conducted, about the Study results.
- 14. Specifications for the partial-walled ultra-clean operating theatre used in the Study.
- 15. Model and serial numbers for the Bair Hugger patient warming device used in the Study.
- 16. Model and serial numbers for the Hot Dog patient warming device used in the Study.
- 17. Model and serial numbers for the Inditherm patient warming device used in the Study.
- 18. Instructions for use of the thermistors (KIMO KH200 Temperature and Humidity Loggers) used in the Study.
- 19. Evidence of the protocol for placement of the thermistors.
- 20. Protocol for taking and recording temperature measurements.
- 21. Statistical Analysis Plan for the Study, including the ANOVA models fitted with the data from the Study.
- 22. Evidence of the final protocols for the Study.
- 23. Communications between and among you, Mark Albrecht and Mark Harper on the subject obtaining forced air warming devices for the study described in the study.

#### **Data and Results of the Study**

- 24. All data generated during the implementation of the Study.
- 25. Records reflecting all measurements taken during the Study, including during set-up.
- 26. All graphic representations generated using data from the Study.
- 27. All results from the statistical analysis of raw data from the Study.
- 28. All photographs taken during the implementation of the Study, including during set-up.
- 29. All video or audio recordings made during the implementation of the Study, including during set-up.
- 30. Communications between and among you, Mark Albrecht and Mark Harper regarding the results of the Study.
- 31. Communications between you and Dr. Scott Augustine regarding the results of the Study;

- 32. Communications between you and Augustine Temperature Management regarding the results of the Study.
- 33. Communications between and among and you and Dr. Scott Augustine regarding raw data for the Study.
- 34. Communications between you and Augustine Temperature Management regarding raw data for the Study.
- 35. Communications between you and Dr. Scott Augustine regarding the analysis or interpretation of the Study results.
- 36. Communications between you and Augustine Temperature Management regarding the analysis or interpretation of the Study results.

#### **Study Publication**

- 37. All pre-publication drafts of the manuscript that was published as Dasari 2012.
- 38. Communications between and among you, Mark Albrecht and Mark Harper regarding Dasari 2012, including the writing of the article.
- 39. Communications between you and Dr. Scott Augustine regarding Dasari 2012, including the writing of the article.
- 40. Communications between you and Augustine Temperature Management regarding Dasari 2012, including the writing of the article.
- 41. Correspondence between you and representatives of the journal Anaesthesia regarding the Study or Dasari 2012.
- 42. All communications from reviewers of Dasari 2012.

#### **Communications with Counsel**

- 43. Communications or correspondence between you and any lawyer or solicitor representing the Defendants in connection with the subject litigation pending in the United States.
- 44. Communications or correspondence between you and any lawyer or solicitor representing any plaintiff in connection with the subject litigation pending in the United States.